

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

CARLOS PÉREZ-COTAPOS UGARTE,
MARIA ISABEL URETA BAZÁN, CARLOS
PÉREZ-COTAPOS SUBERCASEAUX,
INVERSIONES ANE MIREN LIMITADA,
SHERYL GROVE, and HOORIEH
ALAGHEMAND, Individually and on Behalf of
All Others Similarly Situated,

Plaintiffs,

v.

CASSAVA SCIENCES, INC., REMI
BARBIER, RICHARD JON BARRY,
LINDSAY BURNS, JAMES W. KUPIEC, and
ERIC SCHOEN,

Defendants.

Case No.: 1:24-CV-1525-DAE

ORAL ARGUMENT REQUESTED

**NOTICE OF DEFENDANTS REMI BARBIER’S AND LINDSAY BURNS’
MOTION TO DISMISS THE AMENDED COMPLAINT**

PLEASE TAKE NOTICE that, upon the accompanying Memorandum of Law in Support of the Motion to Dismiss the Amended Complaint, the accompanying Declaration of Douglas W. Greene, dated November 6, 2025, and Exhibits 1-3 thereto, the motion to dismiss and memorandum filed by Defendants Cassava, Richard Barry, James Kupiec, and Eric Schoen, and all prior proceedings, pleadings, and filings in this Action, Defendants Remi Barbier and Lindsay Burns, through their counsel Baker & Hostetler LLP, will respectfully move this Court before the Honorable David A. Ezra, United States District Judge, at a time to be determined by the Court, at the United States District Court for the Western District of Texas, Austin Division, 501 West Fifth Street, Austin, Texas 78701, for an Order pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6) and the Private Securities Litigation Reform Act of 1995, dismissing Plaintiffs’ Amended

Complaint (Dkt. #49) in its entirety with prejudice and granting such other relief as the Court may deem just and proper.

Dated: November 6, 2025

Respectfully submitted,

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**MEMORANDUM OF DEFENDANTS REMI BARBIER AND LINDSAY BURNS
IN SUPPORT OF MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT**

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INTRODUCTION

More than four years have passed since short-sellers first attacked Cassava and its lead drug candidate, simufilam. The attack was endlessly highlighted by mass media, and various governmental and institutional investigations have sought to determine what happened and whether any of it amounted to research misconduct. Yet, four years down the road, Plaintiffs still cannot point to any evidence of fraud, and more recent developments show just the opposite. The Amended Complaint (“AC”; ECF 49) relies heavily on an early draft CUNY report leaked to the press,¹ to argue that Dr. Hoau-Yan Wang (and, by association, Dr. Lindsay Burns) engaged in “research misconduct,” but CUNY’s *final* findings—issued in May 2025—explicitly state that it “determined that research misconduct did not occur” with respect to *each of the 31 allegations* leveled against Dr. Wang. *See* Ex. 1 (May 30, 2025 CUNY Letter).² Moreover, the Department of Justice has now *dismissed* its indictment of Dr. Wang, eviscerating Plaintiffs’ contention that the untested accusations in the indictment revealed some hidden truth. *See* Cassava Mot. Ex. D.

As discussed below, and in the motion to dismiss and memorandum filed by Defendants Cassava, Richard Barry, James Kupiec, and Eric Schoen (“Cassava Motion”), Plaintiffs have not come close to meeting the heightened pleading requirements for securities fraud. The AC fails to plead particularized facts showing that any challenged statement was materially false or misleading, a strong inference of scienter, or loss causation. For all the reasons herein and in the Cassava Motion (incorporated here by reference), Plaintiffs’ claims against Defendants Remi Barbier and Dr. Burns should be dismissed with prejudice.

¹ *See* AC ¶¶7, 8, 13, 79, 80, 81, 84, 123, 124, 128, 131, 133, 136, 200, 201. All paragraph (¶) references hereinafter are to the AC, unless otherwise stated.

² The May 30, 2025 letter reporting CUNY’s final findings was publicly filed as an exhibit in *U.S. v. Wang*, No. 8:24-cr-00211 (D. Md., Oct. 14, 2025), ECF 118-2. *Jenkins v. Tahmahkera*, 151 F.4th 739, 747 (5th Cir. 2025) (taking judicial notice of “matters of public record”); *Joseph v. Bach & Wasserman, L.L.C.*, 487 F. App’x 173, 178 n.2 (5th Cir. 2012) (same re court documents).

LEGAL STANDARD

Heightened pleading standards govern Plaintiffs’ securities fraud claims. Under Rule 9(b), all claims sounding in fraud “must state with particularity the circumstances constituting fraud or mistake.” In addition, Plaintiffs must satisfy the heightened pleading requirements of the Private Securities Litigation Reform Act of 1995 (“Reform Act”), which Congress enacted to “set high standards for pursuing federal securities fraud suits in order to check ‘frivolous, lawyer-driven litigation, while preserving investors’ ability to recover on meritorious claims.’” *Ind. Elec. Workers’ Pension Tr. Fund IBEW v. Shaw Grp., Inc.*, 537 F.3d 527, 532 (5th Cir. 2008) (quoting *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 309 (2007)).

The Reform Act requires Plaintiffs to “specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, . . . state with particularity all facts on which that belief is formed.” 15 U.S.C. § 78u-4(b)(1)(B). Plaintiffs thus bear the burden of pleading particular “contemporaneous statements or conditions that render Defendants’ statements false or misleading *when made*.” *In re Sec. Litig. BMC Software, Inc.*, 183 F. Supp. 2d 860, 910 (S.D. Tex. 2001) (emphasis added).

In addition, plaintiffs must, “with respect to each act or omission . . . state with particularity facts giving rise to a strong inference” of scienter—that is, that the particular defendant made the allegedly false or misleading statement intentionally or with severe recklessness that creates “a danger of misleading buyers or sellers which is either known to the defendant or is so obvious that the defendant must have been aware of it.” *Id.* § 78u-4(b)(2)(A); *Al. Elec. Pension Fund v. Asar*, 768 F. App’x 175, 179-80 (5th Cir. 2019). A “strong inference” is “more than merely plausible or reasonable”; it must be “powerful” and “at least as compelling as any opposing inference.” *Tellabs*, 551 U.S. at 323. And in analyzing both falsity and scienter, courts must go beyond the pleadings

to consider the full factual context of the statements and conduct at issue. *Id.* at 323-24; *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 190-91 (2015).

ARGUMENT

I. Dr. Burns and Mr. Barbier Cannot Be Liable for Statements They Did Not Make.

Under *Janus*, only the “maker” of a challenged statement—one “with ultimate authority over the statement”—can be liable under §10(b) and Rule 10b-5. *Janus Capital Group, Inc. v. First Derivative Traders*, 564 U.S. 135, 143 (2011); *Talarico v. Johnson*, 2023 WL 2618255, at *18 (S.D. Tex. Feb. 7, 2023) (“[o]nly those who make statements are liable under § 10b”).

Here, the AC attributes only two challenged statements to Dr. Burns: two slides from a March 2024 presentation conveying certain Phase 2b and Phase 2 open-label study results (¶¶134, 166). The AC does not allege any facts showing that she “made” or had “ultimate authority” over any other challenged statement. Likewise, Mr. Barbier can only be responsible for the statements he personally made or signed (¶¶123, 125, 127, 129, 130, 132, 135, 159, 160, 162-64, 166).

II. None of the Challenged Statements Was False or Misleading.

None of the challenged statements attributed to Mr. Barbier or Dr. Burns was materially false or misleading, as further detailed in the Cassava Motion. An omission, by itself, cannot ground a § 10(b) claim; Plaintiffs must instead plead particularized facts establishing that one or more of Defendants’ affirmative statements was materially false or misleading. *Macquarie Infrast. Corp. v. Moab Partners, L. P.*, 601 U.S. 257, 260 (2024). Moreover, under *Omnicare*, whether a statement is false or misleading “always depends on context” and requires courts to consider not only the statement being challenged and “all its surrounding text, including hedges, disclaimers, and apparently conflicting information” but also other statements made by the company and other publicly available information, including “the customs and practices of the relevant industry.” 575 U.S. at 190-91. This is an objective inquiry “determined from ‘the perspective of a reasonable

investor” who is assumed to be informed about the full context and to incorporate all publicly available information into their decisionmaking. *Heinze v. Tesco Corp.*, 971 F.3d 475, 482 (5th Cir. 2020) (quoting *Omnicare*, 575 U.S. at 186).

Here, the challenged statements attributed to Mr. Barbier or Dr. Burns are of just two types: (1) statements about government, internal, and third-party investigations, and what those investigations had found or conveyed to Defendants at the time (*see* Barbier: ¶¶123, 125, 127, 129-30, 132); and (2) statements interpreting clinical data and conveying results from the Phase 2b and Phase 2 open-label studies (*see* Burns: ¶¶134, 166; *and* Barbier: ¶¶135, 160, 162-64).

As detailed in the Cassava Motion, no factual allegations suggest that any of the challenged statements regarding the leaked CUNY draft report, Orrick’s internal investigation, or the SEC’s and DOJ’s then-ongoing investigations were false or misleading when made. *See* Cassava Mot., Arg. §A.1. Cassava’s October 2023 response to the CUNY committee’s leaked draft report accurately described that report’s contents, Cassava’s lack of involvement in CUNY’s investigative process, and the fact that CUNY’s investigation had not yet concluded (as CUNY itself confirmed shortly thereafter, ¶81). *Id.* Nothing about the Company’s response could have misled a reasonable investor on any of these points, particularly given that the leaked draft report itself was readily publicly available at the time and formed part of the context in which the Company’s statements were viewed. *See Linenweber v. Sw. Airlines Co.*, 693 F.Supp.3d 661, 680 (N.D. Tex. 2023) (statements were “neither false nor misleading when considered in [] context”). Nor does the AC allege any contemporaneous facts that contradicted the Company’s statements in November 2023, February 2024, and May 2024 that, as of that time, “[n]o government agency has informed the Company that it has found evidence of research misconduct or wrongdoing by the Company or its officers, employees or directors” (¶¶125, 127, 132) and that Orrick’s internal

investigation had found “no evidence to substantiate allegations that the Company or its employees engaged in or were aware of research misconduct” (¶¶129-130). Cassava Mot. Arg. §A.1.

Plaintiffs fare no better with respect to the challenged statements interpreting data and reporting results from the Phase 2b and Phase 2 open-label studies. Cassava Mot. Arg. §§ A.2-3. “Courts have repeatedly held publicly stated interpretations of the results of various clinical studies to be opinions because reasonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions.” *In re Sanofi Sec. Litig.*, 87 F.Supp.3d 510, 543 (S.D.N.Y. 2015), *aff’d sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016) (analyzing such statements as opinions under *Omnicare*). Under *Omnicare*, a statement of opinion is only false if the speaker did not actually hold the stated belief, and it is only misleading if particular omitted facts would have rendered the opinion “misleading to a reasonable person reading the statement fairly and in context.” 575 U.S. at 188-89, 194. The AC pleads no facts showing that Mr. Barbier or Dr. Burns did not genuinely believe that the Phase 2b data showed “encouraging effects on cognition” and “statistically significant ... improvements in CSF biomarkers” (¶¶134-135) and that the Phase 2 open-label data showed the reported ADAS-Cog results (¶¶160, 162-164, 166). *See also infra* § III. Nor do Plaintiffs identify any particular omitted fact that rendered these statements misleading in context. Cassava’s audit of Dr. Wang’s lab and the leaked CUNY report largely concerned Dr. Wang’s recordkeeping and did not undermine the challenged statements regarding the Phase 2b results. And the fact that the Company later concluded, in summer 2024, that a May 2020 email from Dr. Burns “could have been used to unblind him as to some number” of subjects and that, in light of that uncertainty, investors “should not place undue reliance” on the Phase 2b biomarker results, does not establish that Dr. Wang was actually unblinded, that the biomarker data were incorrect, or that the challenged statements interpreting

the Phase 2b data were false or misleading. Moreover, the Company extensively disclosed the structure, methodology, and limitations of the Phase 2 open-label study, as well as the fact that the analysis set might differ from that used in earlier or later studies. Cassava Mot. Arg. §A.3. In this context, no reasonable investor could have been misled by the challenged statements describing the Phase 2 open-label study's clinical results. *Id.*

III. Plaintiffs Fail to Plead a Strong Inference of Scienter.

Plaintiffs also fail to plead a strong inference of scienter as to Mr. Barbier or Dr. Burns: no facts suggest that they made any challenged statement intending to deceive investors, and the far more compelling inference is that they acted in good faith. *See Tellabs*, 551 U.S. at 314.

A. Plaintiffs' "Group Pleading" Allegations Are Improper.

As an initial matter, the AC fails to differentiate between the various Defendants when pleading scienter; this in and of itself requires dismissal. The Fifth Circuit has rejected the "group pleading" doctrine and requires plaintiffs to "distinguish among those they sue and enlighten each defendant as to his or her particular part in the alleged fraud." *Owens v. Jastrow*, 789 F.3d 529, 537 (5th Cir. 2015); *Callinan v. Lexicon Pharms., Inc.*, 479 F.Supp.3d 379, 430 (S.D. Tex. 2020), *aff'd*, 858 F.App'x 162 (5th Cir. 2021). Accordingly, a court may not "construe allegations contained in the Complaint against the 'defendants' as a group as properly imputable to any particular individual defendant unless the connection between the individual defendant and the allegedly fraudulent statement is specifically pleaded." *Id.*

Here, the AC is rife with impermissible "group pleading" allegations against "Defendants" generally. *See, e.g.*, ¶¶192, 193, 201, 202, 205, 206, 207, 212, 218, 220, 225, 232, 233, 234. These allegations must be rejected, including as against Dr. Burns and Mr. Barbier. *See, e.g., Owens*, 789 F.3d at 538 ("[W]e disregard the group-pleaded allegations and discern whether the remaining allegations state a claim for relief as to each defendant."); *In re AT&T Inc. Sec. Litig.*, 2025 WL

1685840, at *6 (N.D. Tex. June 16, 2025) (rejecting scienter allegations based on “improper group pleading”).

B. The Absence of Any Alleged Personal Financial Gain Undermines Any Inference of Scienter on the Part of Dr. Burns or Mr. Barbier.

Although a defendant’s motive to defraud is typically a “critical . . . aspect of a successful claim for securities fraud,” *Mun. Emps.’ Ret. Sys. of Mich. v. Pier 1 Imports, Inc.*, 935 F.3d 424, 429-30 (5th Cir. 2019), Plaintiffs do not allege suspicious stock sales or any other concrete financial incentives—this affirmatively *undermines* any inference of scienter. *See, e.g., In re Key Energy Servs., Inc. Sec. Litig.*, 166 F. Supp. 3d 822, 867 (S.D. Tex. 2016) (defendants did not sell their shares during the relevant class period, “undermining any inference of scienter”); *Callinan*, 479 F. Supp. 3d at 434 (no scienter where no “allegations that any [individual defendant] engaged in insider trading or stood to benefit personally from any of the alleged misrepresentations”).

Dr. Burns did not sell any stock during the class period (or before). And Mr. Barbier actually acquired 50,000 stock options during the putative class period on May 20, 2024, Ex. 2 (Barbier Forms 4)³ at 6—long after the August 2021 Citizen’s Petition, the commencement of the SEC investigation in late 2021, the commencement of the DOJ investigation in July 2022, and the October 12, 2023 leaked draft CUNY Report. *See Izadjoo v. Helix Energy Sol. Grp., Inc.*, 237 F.Supp.3d 492, 519 (S.D. Tex. 2017) (stock purchases during class period “weighs strongly against an inference of scienter”). Moreover, even as those developments unfolded in the months leading up to the class period, Mr. Barbier repeatedly acquired—and never sold—Cassava securities, Ex. 2 at 1-5 (reflecting exercise and/or acquisition of 1,051,081 Cassava stock options), setting himself up to be a victim of the fraud Plaintiffs claim he perpetrated. *See In re Sunterra Corp. Sec. Litig.*,

³ *Fin. Acquisition Partners LP v. Blackwell*, 440 F.3d 278, 286 (5th Cir. 2006) (on a motion to dismiss a securities action, the court may rely on documents publicly filed with the SEC).

199 F.Supp.2d 1308, 1328 (M.D. Fla. 2002) (purchase of stock before the class period coupled with no sales during the class period “mitigates in favor of a finding of lack of scienter”).

It makes no sense that Dr. Burns would maintain all her stock holdings in Cassava and that Mr. Barbier would continue to acquire Cassava securities while knowing that the science underlying simufilam and the clinical trials was false or fraudulent. The far more compelling inference is that they acted in good faith: Dr. Burns and Mr. Barbier sold no stock—and Mr. Barbier repeatedly acquired more—because they both believed in the Company and simufilam.

C. Plaintiffs’ Generic and Conclusory Allegations About All “Defendants” Do Not Create a Strong Inference That Dr. Burns or Mr. Barbier Were Motivated To Perpetrate The Fraud Alleged By Plaintiffs.

In the absence of any personal financial gain by Dr. Burns or Mr. Barbier, Plaintiffs are again reduced to improper “group pleading.” Plaintiffs allege that all “Defendants”—collectively—“were motivated to mislead investors” (1) “in order to make simufilam’s prospects appear better and garner support for the drug’s continued development”, and (2) “in order to raise capital critical for the continued development of simufilam.” ¶¶220-227, 232. Because these allegations are attributed to all six “Defendants” and do not contain *any* particularized allegations regarding Dr. Burns or Mr. Barbier, they are patently insufficient. *See Owens*, 789 F.3d at 538; *In re AT&T*, 2025 WL 1685840, *6; *Callinan*, 479 F. Supp. 3d at 430.

Moreover, it is well-established that neither the alleged desire to “make [a product] look beneficial” nor the alleged “desire to raise capital” creates an inference of fraudulent intent because “virtually all corporate insiders share th[ese] goal[s].” *Neiman v. Bulmahn*, 854 F.3d 741, 748 (5th Cir. 2017) (rejecting scienter based on desire to raise capital); *Ho v. Flotek Indus., Inc.*, 248 F.Supp.3d 847, 859 (S.D. Tex. 2017) (rejecting scienter based on desire to make product “look beneficial”), *aff’d sub nom. Alaska Elec. Pension Fund v. Flotek Indus., Inc.*, 915 F.3d 975 (5th Cir. 2019); *Owens*, 789 F.3d at 539 (similar); *Abrams v. Baker Hughes Inc.*, 292 F.3d 424, 434

(5th Cir. 2002) (similar). This principle applies equally to a clinical-stage biotech company’s desire to raise capital for drug development and secure regulatory approval, even where those are alleged to be necessary for the company to “survive.” *Callinan*, 479 F. Supp. 3d at 428-437.

D. The AC Fails to Plead Strong Circumstantial Evidence that Dr. Burns or Mr. Barbier Perpetrated the Fraud Alleged By Plaintiffs.

Having failed to plead any cognizable motive, “the strength of [Plaintiffs’] circumstantial evidence of scienter must be correspondingly greater.” *Pier 1 Imports*, 935 F.3d at 429-30. As discussed below, the AC is devoid of particularized allegations showing that Mr. Barbier or Dr. Burns knew any specific challenged statement was false or intended to deceive investors.

Dr. Burns. The vast majority of Plaintiffs’ scienter allegations fail even to mention, much less plead any particularized facts concerning, Dr. Burns, and must be rejected as improper “group pleading.” *See supra* § III.A; ¶¶212-219 (“Access to and Review of the Phase 2 Study Results”); ¶¶228-234 (“Core Operations”). The only circumstantial allegations specifically relating to Dr. Burns’s scienter are that: (1) Dr. Burns “played a critical role in the development of simufilam”; (2) on May 14, 2020, she allegedly “sent Dr. Wang a document that enabled him to unblind himself as to some patients in the Phase 2b Study”; (3) she “received the results of cognition testing during the Phase 2b Study, which showed no meaningful improvement in patient cognition, and while unblinded, she removed 40% of the patient population from the final results”; (4) she was “generally aware” of the findings in Cassava’s September 2022 audit of Dr. Wang’s lab; and (5) she was “aware” of accusations of misconduct in connection with the Phase 2b trial as a result of the “Citizen’s Petition, news articles reporting on the controversy and resulting investigations, the publicly available September 2022 FDA inspection report . . . the CUNY Report . . . and the various lawsuits filed against the Company and its executives beginning in 2021.” ¶¶197, 200, 201, 204. None of these allegations—separately or together—establishes a strong inference that Dr. Burns

reported the Phase 2b and open-label study results in the March 2024 presentation knowing that they were false or intending to mislead investors.

First, that Dr. Burns “played a critical role in the development of simufilam” says nothing about whether she had a fraudulent state of mind. “[P]leadings of scienter may not rest on the inference that defendants must have been aware of the misstatement based on their positions with the company.” *Shaw Grp., Inc.*, 537 F.3d at 535; accord *In re Repros Therap., Inc. Sec. Litig.*, 2010 WL 11583428, at *10 (S.D. Tex. Nov. 17, 2010). Her role in the development of simufilam cannot, on its own, establish that she knew the clinical results in the May 2024 presentation were false or misleading; indeed, as detailed *supra* and in the Cassava Motion, no facts establish the falsity of those statements, much less her fraudulent intent. *Supra* §II; Cassava Mot. Arg. §§A2-3.

Second, Plaintiffs’ conclusory assertions that Dr. Burns sent Dr. Wang a May 14, 2020 email that allegedly could have unblinded him, and that she “received the [Phase 2b] results” showing “no meaningful improvement in patient cognition” and “removed 40% of the patient population from the final results,” cannot establish scienter. Rather than provide factual support for these assertions—through confidential witness allegations or otherwise—Plaintiffs purport to rely on untested allegations in the SEC’s September 26, 2024 complaint asserting *negligence* claims. ¶154. However, “untested assertions” by the SEC cannot establish scienter, particularly where, as here, the SEC asserted non-scienter *negligence* claims, not intentional wrongdoing, and those claims were settled on a no-admit no-deny basis. *In re UBS Auction Rate Sec. Litig.*, 2010 WL 2541166, at *19 n.11 (S.D.N.Y. June 10, 2010) (SEC lawsuit and settlement of negligence claims on no-admit no-deny basis constitute “untested assertions made by litigants” that are “not binding on this Court”) (collecting cases); *In re Enron Corp. Sec., Deriv. & “ERISA” Litig.*, 2003 WL 23305555, at *11 (S.D. Tex. Dec. 11, 2003) (“settle[ments] with various regulatory agencies

. . . are too vague and general as circumstantial fact allegations . . . to establish scienter”). Indeed, that the SEC “uncovered no evidence of fraud” only serves to make opposing non-culpable inferences “more compelling.” *In re Ceridian Corp. Sec. Litig.*, 542 F.3d 240, 248 (8th Cir. 2008).

Moreover, Plaintiffs fail to plead any facts showing *how* the May 14, 2020 email could have or did cause Dr. Wang to become unblinded, much less any facts establishing that Dr. Burns knew that to be the case at the time of the May 2024 presentation. Cassava Mot., Arg. §B. Similarly, Plaintiffs fail to provide any explanation or details about Dr. Burns’s alleged removal of patients from the Phase 2b results; any factual support for the conclusory assertion that this rendered the Phase 2b results false or misleading in context; or any facts suggesting Dr. Burns knew or was reckless in not knowing that the results were false or misleading. *Id.*

Third, that certain individuals at Cassava conducted a routine vendor audit of Dr. Wang’s lab in September 2022, long after the conclusion of the Phase 2b trial in September 2020 (§62), and concluded that the lab was “unacceptable” for Cassava’s purposes in the “future” does not establish that Dr. Burns knew or believed the *Phase 2b results* were false (the audit did not concern or otherwise address the Phase 2b study results). Cassava Mot., Arg. §B. Indeed, Plaintiffs fails to allege any facts regarding when, how, or if Dr. Burns ever received or was made aware of the audit; they merely allege—without any factual support—that she was “generally aware” of the audit’s findings. Such sparse and vague allegations are insufficient to plead scienter under Fifth Circuit precedent. *See Jacobowitz v. Range Res. Corp.*, 596 F.Supp.3d 659, 687 (N.D. Tex. 2022) (no scienter where plaintiffs failed to plead facts showing “when the reports . . . were presented to Defendants, or whether Defendants actually saw the reports”); *In re BP p.l.c. Sec. Litig.*, 852 F.Supp.2d 767, 817 (S.D. Tex. 2012) (same; “Plaintiffs provide no details regarding the contents of the reports [defendant] received, [or] whether [defendant] was the determined recipient”); *see*

also Delaware Cnty. Emps. Ret. Sys. v. Cabot Oil & Gas Corp., 579 F.Supp.3d 933, 954 (S.D. Tex. 2022) (“General allegations that the defendants received reports with material information are not sufficient to create a strong inference of scienter.”); *Yang v. Nobilis Health Corp.*, 2021 WL 3619863, at *2 (5th Cir. Aug. 13, 2021) (“Mere proximity to information does not automatically translate to knowledge of it.”).

Fourth, neither of the third-party CUNY and FDA inquiries regarding Dr. Wang’s lab are alleged to have addressed or made any findings with respect to the Phase 2b or open-label trial results. The AC does not allege facts showing that Dr. Burns knew of these inquiries at any time, but even if she did, it would not show that she knew the Phase 2b or open-label trial results were false or misleading. Cassava Mot., Arg. §B.

Fifth, that certain outside short sellers, reporters, and plaintiffs publicly accused Dr. Wang and the Company of research misconduct does not establish that the Phase 2b and open-label results shared in the March 2024 presentation were false or misleading, or that Dr. Burns knew or believed such allegations to be true at the time. None of the sources of these allegations were insiders at Cassava or CUNY, or alleged to have been in any contact with Dr. Burns, and had no basis to know whether the clinical results presented in the March 2024 presentation were false or misleading, or what Dr. Burns knew or believed about those results at any time. Plaintiffs have not pleaded sufficient detail to establish the “reliability” of these outside sources or whether their allegations were based on a “credible investigative effort.” *Gambrill v. CS Disco, Inc.*, 2025 WL 388828, at *12 (W.D. Tex. Jan. 30, 2025); *id.* (“[N]ewspaper articles should be credited only to the extent that other factual allegations would be—if they are sufficiently particular and detailed to indicate their reliability. Conclusory allegations of wrongdoing are no more sufficient if they come from a newspaper article than from plaintiff’s counsel.”).

Because none of these scienter allegations are well-pleaded or supported by particularized facts, they cannot raise a strong inference of scienter as to Dr. Burns and are outweighed by the competing inferences of good faith.

Mr. Barbier. The AC is also devoid of particularized facts showing that Mr. Barbier made any challenged statement knowing that it was false or misleading or intending to deceive investors. The AC attributes two types of challenged statements to Mr. Barbier: (1) statements about what CUNY’s leaked draft report, the SEC and DOJ, and Orrick had found or conveyed about their investigations (e.g., “[n]o government agency has informed the Company that it has found evidence of research misconduct or wrongdoing by the Company or its officers, employees, or directors” (¶¶125, 127, 132); Orrick’s internal investigation “found no evidence to substantiate allegations that the Company or its employees engaged in or were aware of research misconduct” (¶¶129, 130)); and (2) statements describing the results of the Phase 2b trial and Phase 2 open-label extension (¶¶160, 162-164, 166). All statements in the first category were literally true, and the statements regarding clinical results were true and not misleading opinions, expressing the Company’s subjective interpretation of the study data. *Supra* §II; Cassava Mot., Arg. §§A.2-3.

Plaintiffs fail to plead strong circumstantial evidence of scienter against Mr. Barbier regarding any of these statements, for many of the same reasons discussed above with respect to Dr. Burns. The sum total of Plaintiffs’ circumstantial allegations against Mr. Barbier is as follows: (1) Mr. Barbier was the CEO of Cassava and “managed the day-to-day affairs of the Company” (¶¶193-194); (2) “[b]ased on [his] position,” Mr. Barbier “had access to data underlying the Phase 2 Study Results” (¶216); (3) Mr. Barbier “knew or should have known” that the October 12, 2023 response to the CUNY Report was false or misleading because Cassava “had in its possession Burns’ May 14, 2020 email to Dr. Wang”; (4) Mr. Barbier is married to Dr. Burns, and thus

“presumably spoke about the controversy” with her (§200); (5) Mr. Barbier was “generally aware” of the findings in Cassava’s September 2022 audit (§204); and (6) Mr. Barbier was “aware” of accusations of misconduct in connection with the Phase 2b trial as a result of the “Citizen’s Petition, news articles reporting on the controversy and resulting investigations, the publicly available September 2022 FDA inspection report . . . the CUNY Report . . . and the various lawsuits filed against the Company and its executives beginning in 2021” (§§201, 217, 222).

Here, again, Plaintiffs cannot establish a strong inference of scienter merely by virtue of Mr. Barbier’s position at the Company. *Supra* at 10; (§§193-194, 216). Moreover, the conclusory assertion that he had “access to the data underlying the Phase 2 Study Results” is insufficient to show when, how, or what he knew about that data. Absent facts describing specific reports Mr. Barbier received related to the Phase 2 data, when he received them, or what they said, this cannot support an inference of scienter. *Supra* at 11-12.

Likewise, Plaintiffs’ conclusory allegations that Cassava “had in its possession Burns’ May 14, 2020 email to Dr. Wang” says nothing about whether or when *Mr. Barbier* ever became aware of that email, and the mere fact that Mr. Barbier is married to Dr. Burns cannot establish with particularity what *Mr. Barbier* knew or when regarding any alleged misconduct. *Supra* at 11-12. *See, e.g., In re DraftKings Inc. Sec. Litig.*, 650 F. Supp. 3d 120, 178 (S.D.N.Y. 2023) (personal relationship with direct report does not establish strong inference of knowledge or scienter); *Weiss v. Amkor Tech., Inc.*, 527 F. Supp. 2d 938, 952 (D. Ariz. 2007) (“[Defendant’s] personal relationship [marriage] . . . does not strongly compel an inference of scienter”); *see also In re Plains All Am. Pipeline, L.P. Sec. Litig.*, 245 F. Supp. 3d 870, 892 (S.D. Tex. 2017) (“[P]laintiffs cannot simply point to the fact that some other person at the corporation knew of facts that make the statement misleading and impute that knowledge to the speaker.”).

As for vague allegations that Mr. Barbier was “generally aware” of the September 2022 Cassava audit and various public accusations of misconduct, these fail to plead any particularized facts establishing what exactly Mr. Barbier knew, when, or how it was inconsistent with any of his challenged statements. *Supra* at 11-12.

E. The “Core Operations” Theory Does Not Salvage Plaintiffs’ Claims.

The “core operations” doctrine is an extremely narrow exception to the rule that “a pleading of scienter may not rest on the inference that defendants must have been aware of the alleged misconduct ‘based on their positions within the company.’” *Crutchfield v. Match Grp., Inc.*, 529 F.Supp.3d 570, 603 (N.D. Tex. 2021). Indeed, “the Fifth Circuit has stated that only in the ‘rare case’ will a strong inference of scienter be drawn from an officer’s position in a company, and only when this factor combines with other, ‘special circumstances.’” *Callinan*, 479 F.Supp.3d at 435. Such circumstances may include: “(1) a small company in which corporate executives are more likely to be familiar with day-to-day operations; (2) transactions ‘critical to the company’s continued vitality’; (3) omitted information readily apparent to the speaker; and (4) statements by the corporate officer that are internally inconsistent.” *Id.*

Here, Plaintiffs fail to plead three of the four “special circumstances.” First, Plaintiffs fail to adequately plead that the development of simufilam for the treatment of Alzheimer’s was “critical to [Cassava’s] continued vitality.” The Company is continuing to develop simufilam for the treatment of epilepsy—with promising results—and remains vital even after the Company turned away from its Alzheimer’s program. *Callinan*, 479 F.Supp.3d at 436 (rejecting conclusory allegations that biotech company was “dependent on [drug’s] approval to survive”). Second, Plaintiffs fail to plead any specific “omitted information readily apparent to” Dr. Burns or Mr. Barbier that contradicted their challenged statement. *Supra* 11; Cassava Mot., Arg., §§A.3-4. Plaintiffs fail to demonstrate that any statement they challenge was false or misleading, much less

so blatantly false or misleading as to warrant application of this “special circumstance.” Finally, Plaintiffs fail to allege that Dr. Burns or Mr. Barbier made any internally inconsistent statements. *Crutchfield*, 529 F.Supp.3d at 604 (“core operations” allegations insufficient for failure to plead omitted information or internally inconsistent statements); *Callinan*, 479 F.Supp.3d at 436 (similar). In these circumstances, the core operations doctrine cannot establish a strong inference of scienter as to Mr. Barbier or Dr. Burns.

IV. Plaintiffs Fail to Plead Loss Causation for Any Challenged Statement Attributed to Dr. Burns or Mr. Barbier.

Plaintiffs’ claims against Mr. Barbier and Dr. Burns also fail for a separate, independently dispositive reason: no factual pleadings show the requisite “causal connection” between any of their challenged statements and Plaintiff’s alleged economic loss. *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 342 (2005); 15 U.S.C. § 78u-4(b)(4); *see also* Cassava Mot., Arg. §B.

To plead loss causation as to Mr. Barbier or Dr. Burns, Plaintiffs must allege facts showing that the partial corrective disclosures identified in the AC revealed the truth allegedly hidden by their challenged statements. *See Heck v. Orion Grp. Holdings, Inc.*, 468 F.Supp.3d 828, 860 (S.D. Tex. 2020) (corrective disclosure “must reflect part of the ‘relevant truth’ – the truth obscured by the fraudulent statements”). “A complaint does not plausibly allege loss causation when the disclosed information has already been revealed to the market.” *Stephens v. Uranium Energy Corp.*, 2016 WL 3855860, at *20 (S.D. Tex. July 15, 2016) (citing *Greenberg v. Crossroads Sys., Inc.*, 364 F.3d 657, 665–66 (5th Cir. 2004)). Likewise, “commencement of government investigations on suspected fraud do not, standing alone, amount to a corrective disclosure.” *Budde v. Glob. Power Equip. Grp., Inc.*, 2017 WL 6621540, at *5 (N.D. Tex. Dec. 27, 2017).

Here, none of the alleged partial corrective disclosures—Dr. Wang’s indictment; July 1, August 8, and September 26, 2024 press releases; and announcement of the Phase 3 trial results—

“corrected” or revealed any truth previously hidden by the challenged statements attributed to Mr. Barbier or Dr. Burns. As detailed above, the AC attributes just two challenged statements to Dr. Burns, both interpreting data from the Phase 2b and open-label studies. *Supra* at 3. And the challenged statements attributed to Mr. Barbier were limited to statements about the same clinical results along with statements regarding the limited scope of the draft CUNY report and its findings, what government agencies had told the Company (“[n]o government agency has informed the Company that it has found evidence of research misconduct or wrongdoing by the Company or its officers, employees, or directors” (¶¶125, 127, 132), and that Orrick’s internal investigation found no evidence that Cassava employees were “engaged in or [] aware of research misconduct” (¶130).

All of these were truthful statements of fact or opinion, and none were “corrected” by the alleged partial corrective disclosures. *See Stephens*, 2016 WL 3855860, at *12 (dismissing because alleged corrective disclosures did not reveal any hidden “‘relevant truth’ about the [alleged] fraud”). The June 28, 2024 indictment of Dr. Wang did not disclose any fraud or wrongdoing by Dr. Burns, Mr. Barbier, or Cassava, nor did it reveal any previously hidden truth about Cassava’s clinical results, the CUNY Report’s findings, Orrick’s internal investigation, or what any government agency told Cassava earlier about their investigations. ¶239. Mere filing of a government complaint is insufficient to establish the truth of any of its untested allegations or to “correct” any earlier statement inconsistent with those allegations. *See Genesee Cnty. Employees’ Ret. Sys. v. FirstCash Holdings Inc.*, 667 F.Supp.3d 295, 330 (N.D. Tex. 2023) (government complaint “devoid of anything but allegations” is “not a final finding or ruling that the defendants have violated the law” and “is not a corrective disclosure”). Indeed, that CUNY ultimately “determined that research misconduct did not occur” (Ex. 2), and the DOJ recently dismissed its indictment against Dr. Wang after conducting a four-year investigation, only underscores that the

commencement of an investigation or proceeding against an individual cannot establish loss causation absent a determination of wrongdoing. *FirstCash*, 667 F.Supp.3d at 330. But even taking at face value the indictment’s allegations—which were not the subject of any challenged statements—those allegations were already well-known to the market, beginning with the August 2021 Citizen’s Petition (and the subsequent securities class), and through the October 2023 leaked draft CUNY report. Because disclosure of Dr. Wang’s indictment in June 2024 did not reveal any new truth previously hidden by any challenged statement, it cannot establish loss causation. *Supra* at 1; *Magruder v. Halliburton Co.*, 359 F.Supp.3d 452, 462 n.4 (N.D. Tex. 2018) (no loss causation where information was previously disclosed in *Wall Street Journal* article).

Nor could the July 1, August 8, or September 26, 2024 disclosures reveal any truth previously hidden by the challenged statements. The disclosures related to the SEC and DOJ investigations and the SEC complaint and settlement (§§240, 243, 244), addressed investigations and allegations that had already been disclosed years earlier (on Nov. 17, 2021 for the SEC; and on July 27, 2022 for the DOJ) (§§73-76). The “commencement of government investigations on suspected fraud do not, standing alone, amount to a corrective disclosure.” *Budde*, 2017 WL 6621540, at *5. The DOJ has not brought any charges against Cassava, Dr. Burns, or Mr. Barbier, and the SEC complaint alleged only *negligence* (non-fraud) claims, which Cassava, Dr. Burns, and Mr. Barbier settled on a no-admit no-deny basis. *FirstCash*, 667 F.Supp.3d at 330. The Company’s July 1 announcement that a May 14, 2020 email to Dr. Wang “could have been used to unblind him as to some number of the Phase 2b Study participants” and that investors should not place “undue reliance” on the Phase 2b results, did not reveal whether that email in fact unblinded Dr. Wang *or* impacted the Phase 2b results. Moreover, the Company had previously, explicitly warned, in the May 2024 presentation itself, that: “[O]ur clinical results from earlier-stage clinical trials

may not be indicative of full results or results from later stage or large-scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on our earlier-stage clinical trials results we present or publish.” Ex. 4.⁴

The remaining alleged corrective disclosures each concerned the results of the *Phase 3* trial (¶¶248-250), not the Phase 2b or open-label trials, and therefore could not “correct” Dr. Burns’s or Mr. Barbier’s challenged statements, which concerned different subjects. *Callinan*, 479 F.Supp.3d at 440 (failure to obtain FDA approval did not “correct” statements about Phase 2 and 3 results). As for Plaintiffs’ “materialization of the risk” assertions regarding the Phase 3 results, “[t]he Fifth Circuit has not adopted the materialization-of-the-risk theory” and “[d]oing so may be foreclosed by the Fifth Circuit’s analysis of loss causation in” *Catogas v. Cyberonics, Inc.*, 292 F.App’x 311 (5th Cir. 2008) and *Alaska Elec. Pension Fund v. Flowserve Corp.*, 572 F.3d 221, 227 (5th Cir.2009). *Dawes v. Imperial Sugar Co.*, 975 F.Supp.2d 666, 709 (S.D. Tex. 2013); *In re Dell Inc., Sec. Litig.*, 591 F.Supp.2d 877, 911 & n.3 (W.D. Tex. 2008). And even if Fifth Circuit law permitted such a theory, the March 2024 presentation and other Cassava disclosures repeatedly warned of the risk that the Phase 3 trials might not be successful. *Supra* at 19. “Statements about the materialization of risks that the Company has previously disclosed and warned against are not corrective disclosures” and cannot establish loss causation. *In re Key Energy Servs., Inc. Sec. Litig.*, 166 F.Supp.3d at 865.

V. Plaintiffs Fail to Plead Control Person Liability.

Because Plaintiffs have failed to plead a primary § 10(b) violation against any Defendant,

⁴ The March 2024 Presentation is incorporated by reference into the AC (¶¶84, 134, 166) and is otherwise judicially noticeable. *See Basic Cap. Mgmt., Inc. v. Dynex Cap., Inc.*, 976 F.3d 585, 589 (5th Cir. 2020) (court “must consider . . . documents incorporated into the complaint by reference” on motion to dismiss) (quoting *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011); *Jenkins*, 151 F.4th at 747 (judicial notice of matters of public record is proper on a motion to dismiss).

their § 20(a) control-person claims against Mr. Barbier and Dr. Burns fail as well. *Asar*, 768 F.App’x at 189.

The § 20(a) claim against Dr. Burns also fails for the additional reason that she is not sufficiently alleged to have been a “control person.” To establish control-person liability, a plaintiff “must plead facts indicating that defendants . . . ‘had the requisite power to directly or indirectly control or influence corporate policy.’” *In re BP p.l.c. Sec. Litig.*, 922 F.Supp.2d 600, 640 (S.D. Tex. 2013). The sum total of Plaintiffs’ control-person allegations against Dr. Burns are the conclusory assertions that she held a “senior position” as a “senior officer” at Cassava, and that she “participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company’s business affairs.” ¶¶274-277. But Plaintiffs fail to plead facts supporting any of these vague assertions or establishing that she “had the requisite power to directly or indirectly control or influence corporate policy” or that she “controlled” any other defendant. To the contrary, Dr. Burns was not a director or officer of Cassava, and she was not otherwise a member of the Company’s executive management. ¶¶45-46 (describing her as Cassava’s “Senior Vice President of Neuroscience” who reported to Mr. Kupiec, the Chief Medical Officer). And it is well-established that “[s]tatus alone as to persons not involved in day to day management is legally insufficient to support a Section 20(a) claim.” *Zishka v. Am. Pad & Paper Co.*, 2001 WL 1748741, at *1 (N.D. Tex. Sept. 28, 2001), *aff’d*, 72 F. App’x 130 (5th Cir. 2003). Because no factual pleadings establish Dr. Burns’s “control” over Cassava or any individual defendant, the §20(a) claim against her must be dismissed.

CONCLUSION

For all of these reasons, and those detailed in the Cassava Motion, Defendants Barbier and Burns respectfully ask that the Court dismiss all claims against them with prejudice.

DATED: November 6, 2025

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